



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 862**

**[Docket No. FDA-2018-N-3648]**

### **Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Insulin Therapy Adjustment Device**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the insulin therapy adjustment device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the insulin therapy adjustment device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The classification was applicable on June 12, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993-0002, 301-796-2411, [Dina.Jerebitski@fda.hhs.gov](mailto:Dina.Jerebitski@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

Upon request, FDA has classified the insulin therapy adjustment device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and

Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

## II. De Novo Classification

On August 17, 2017, DreaMed Diabetes, Ltd., submitted a request for De Novo classification of the DreaMed Advisor Pro. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 12, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 862.1358. We have named the generic type of device insulin therapy adjustment device, and it is identified as a device intended to incorporate biological inputs, including glucose measurement data from a continuous glucose monitor, to recommend insulin therapy adjustments as an aid in optimizing insulin therapy regimens for patients with diabetes mellitus.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Insulin Therapy Adjustment Device Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Erroneous or extreme changes in insulin dosing recommendations may cause hypoglycemia or hyperglycemia.	Special controls (1) (21 CFR 862.1358(b)(1)), (2) (21 CFR 862.1358(b)(2)), and (3) (21 CFR 862.1358(b)(3))
Incorrect interpretation of results may lead to inappropriate clinical decision making.	Special controls (1) (21 CFR 862.1358(b)(1)) and (3) (21 CFR 862.1358(b)(3))
Incorrect understanding of appropriate device use may lead to inappropriate treatment decisions.	Special controls (1) (21 CFR 862.1358(b)(1)), (2) (21 CFR 862.1358(b)(2)), and (3) (21 CFR 862.1358(b)(3))
Patient harm due to insecure transmission of data.	Special control (1) (21 CFR 862.1358(b)(1))
Data corruption may lead to inappropriate treatment recommendations.	Special control (1) (21 CFR 862.1358(b)(1))

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

### III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910-0485.

#### **List of Subjects in 21 CFR Part 862**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

#### **PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES**

1. The authority citation for part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 862.1358 to subpart B to read as follows:

#### **§ 862.1358 Insulin therapy adjustment device.**

(a) *Identification.* An insulin therapy adjustment device is a device intended to incorporate biological inputs, including glucose measurement data from a continuous glucose monitor, to recommend insulin therapy adjustments as an aid in optimizing insulin therapy regimens for patients with diabetes mellitus.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include the following:

(i) A complete description of the required data inputs, including timeframe over which data inputs must be collected and number of data points required for accurate recommendations;

(ii) A complete description of the types of device outputs and insulin therapy adjustment recommendations, including how the recommendations are generated;

(iii) Robust data demonstrating the clinical validity of the device outputs and insulin therapy recommendations;

(iv) A robust assessment of all input data specifications, including accuracy requirements for continuous glucose monitors and other devices generating data inputs, to ensure accurate and reliable therapy adjustment recommendations. This assessment must include adequate clinical justification for each specification;

(v) A detailed strategy to ensure secure and reliable means of data transmission to and from the device, including data integrity checks, accuracy checks, reliability checks, and security measures;

(vi) Robust data demonstrating that users can understand and appropriately interpret recommendations generated by the device; and

(vii) An appropriate mitigation strategy to minimize the occurrence of dosing recommendation errors, and to mitigate the risk to patients of any residual dosing recommendation errors to a clinically acceptable level.

(2) The device must not be intended for use in implementing automated insulin dosing.

(3) Your 21 CFR 809.10(b) labeling must include:

(i) The identification of specific insulin formulations that have been demonstrated to be compatible with use of the device;

(ii) A detailed description of the specifications of compatible devices that provide acceptable input data (e.g., continuous glucose monitors, insulin pumps) used to provide accurate and reliable therapy adjustment recommendations;

(iii) A detailed description of all types of required data (inputs) and dosing recommendations (outputs) that are provided by the device; and

(iv) A description of device limitations, and instructions to prevent possible disruption of accurate therapy adjustment recommendations (e.g., time zone changes due to travel).

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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